General

Guideline Title

Genetic counselling and testing. In: Guidelines for preventive activities in general practice, 8th edition.

Bibliographic Source(s)

Genetic counselling and testing. In: Guidelines for preventive activities in general practice, 8th edition. East Melbourne (Australia): Royal Australian College of General Practitioners; 2012. p. 14-6.

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

The levels of evidence (I-IV, Practice Point) and grades of recommendations (A-D) are defined at the end of the "Major Recommendations" field.

There is evidence to recommend offering specific genetic tests to pregnant women, couples planning a pregnancy and neonates (as part of the newborn screening program) (C). Other genetic tests are appropriate for certain conditions where the individual is considered to be at increased risk (A).

In order to identify patients who may potentially benefit from genetic testing, the general practitioner (GP) must ensure that a comprehensive family history is taken from all patients including first-degree or second-degree relatives (A) and regularly updated. A family history should ideally extend to 3 generations, covering both sides of the family and ethnic background. Age of onset of disease and age of death should be recorded where available.

The presence of genetically determined disease may be suggested by increased frequency and early onset of cancers in families, premature ischaemic heart disease or sudden cardiac death, intellectual disability, multiple pregnancy losses, stillbirth or early death and children with multiple congenital abnormalities. Also, patients of particular ethnic backgrounds may be at increased risk and benefit from genetic testing for specific conditions. Possible consanguinity (cousins married to each other) should be explored, for example, by asking, 'Is there any chance that a relative of yours might be related to someone in your partner's family?' GPs should consider referral to or consultation with a genetic service (general or cancer genetics) for testing because test results, (which rely on sensitivity, specificity and positive predictive value) are not straightforward. Testing often involves complex ethical, social and legal issues. Waiting lists for genetic services are usually more than 1 month, so direct consultation and liaison by telephone are necessary when the genetic advice could affect a current pregnancy.

Genetic Testing: Identifying Risks

Who Is at Risk?	What Should Be Done?	How Often?	References
Breast and Ovarian Cancer			
See the NGC summary of The Royal Australian College of General Practitioners (RACGP) guideline Early detection of cancers.			
Colon Cancer			
See the NGC summary of RAGCP guideline Early detection of cancers.			
Familial Hypercholesterolaemia (FH)			
Increased Risk • Premature ischaemic heart disease (men aged <55 years, women aged <60 years) • First-degree relative with premature ischaemic heart disease (men aged <55 years, women aged <60 years) • Total cholesterol >7.5 or low density lipoprotein-cholesterol (LDL-C) >4.9 • First-degree relative with a total cholesterol >7.5 or LDL-C >4.9 • Tendon xanthomata or arcus cornealis at age <45 years	Assess their probability of having FH using the Dutch Lipid Clinic Network (DLCN) criteria or Modified UK Simon Broome (MUKSB) criteria. (III,B) (See Appendix 1 in the original guideline document.) Offer referral to a lipid disorders clinic if DLCN score >3 or the MUKSB suggests possible FH.	At first presentation	World Health Organization, 1999; Watts et al., 2011; The Cardiac Society of Australia and New Zealand, 2010
Cystic Fibrosis (CF)			
Increased Risk • Northern European or Ashkenazi Jewish ancestry • Family history of CF, or a relative with a known CF mutation • Where partner is affected or is a known carrier of CF • Partners from Northern European, Ashkenazi Jewish backgrounds who are consanguineous (cousins married to each other) • Men with infertility suspected or due to congenital absence of the vas deferens	Offer referral for genetic counselling and testing. (III,B) If patient is pregnant, contact genetic services to organise screening in first trimester.	Test couple prior to pregnancy or in first trimester	Lees & Smythe, 2000; Merelle et al., 2001; Genetics Education in Medicine Consortium, 2008
Down Syndrome			
At Risk All pregnant women	Combined maternal serum and ultrasound screening in first trimester Maternal serum screening in second trimester* (C)	In first or second trimester	Genetics Education in Medicine Consortium, 2008; Facher & Robin, 2000; Dick, 1996; American College of Obstetricians and Gynecologists, 2007; Centre for Genetic Education, 2011
Significantly Increased Risk • Women who have had a previous Down syndrome pregnancy • Women with positive maternal serum screening/nuchal translucency ultrasound in first trimester or maternal	Foetal diagnostic genetic testing (C) Offer referral for genetic counseling.	In first or second trimester	Facher & Robin, 2000

Who Is at Risk?	What Should Be Done?	How Often?	References
serum screening in second trimester • Parent with a chromosomal rearrangement (e.g., balanced translocation of chromosome 21)			
Hereditary Haemochromatosis (HFE)			
Increased Risk • Patients with liver disease of unknown cause, including those with suspected alcoholic liver disease • All first-degree relatives of patients with haemochromatosis, known mutation in HFE gene • Patients with conditions that could be a complication of HFE (diabetes mellitus, atypical arthritis, cardiomyopathy, erectile dysfunction or chronic fatigue)	Test for transferrin saturation and serum ferritin concentration. If fasting transferrin saturation >45% or fasting ferritin >250 µg/L on more than one occasion, test for HFE mutations. (II,A) If HFE mutation identified, discuss options for genetic testing and referral for genetic counselling of at-risk family. Children of C282Y heterozygotes should only be tested if the other parent has the C282Y mutation. Testing children in affected families is generally not recommended until age 18 years unless symptomatic. Other first-degree relatives of C282Y heterozygotes should be tested with iron studies. If these are positive, discuss genetic testing and referral for genetic counseling.	At first presentation	Genetics Education in Medicine Consortium, 2008; Emery et al., 2007; Powell et al., 2006; Bacon et al., 2011
Haemoglobinopathies and Thalassaemias			
Increased Risk • People from any of the following ethnic backgrounds: Southern European, African (including Americas and Caribbean), Middle Eastern, Chinese, Indian subcontinent, Central and South East Asian, Pacific Islander, New Zealand Maori, South American and some northern Western Australian and Northern Territory Indigenous communities	Mean corpuscular volume, mean corpuscular haemoglobin, ferritin Haemoglobin electrophoresis (III,B) Seek advice from haematology or genetic services about deoxyribonucleic acid (DNA) testing especially for alpha-thalassaemia carriers.	Test couple prior to pregnancy or in first trimester	Bacon et al., 2011; Pagon et al., 2010
Fragile X Syndrome			
Increased Risk Children or adults of either sex with one or more of the following features:	Karyotype/comparative genomic hybridisation by microarray and DNA test for fragile X	Any age for diagnosis	Cohen & Lennox, 1999; Mefford, Batshaw, & Hoffman, 2012

Who Is at Risk?	What Should Be Done?	How Often?	References
• Developmental delay including intellectual disability of unknown cause • Autistic-like features • Attention deficit hyperactivity disorder • Speech and language problems • Social and emotional problems, such as aggression or shyness	Refer to genetic services for genetic counselling and testing at-risk family. (I,A)	Prior to pregnancy to ascertain reproductive risk	
• A female with a history of primary ovarian insufficiency or premature menopause (age <40 years)	(IV,B)		Jean Hailes Foundation, 2003; Laml et al., 2002
• Adults with ataxia, balance problems and Parkinsonism • Relative with a fragile X mutation	(IV,A)		Jacquemont et al., 2004

*First trimester Down syndrome screening:

Free beta human chorionic gonadotrophin (HCG), pregnancy associated plasma protein at 10 to 12 weeks (this also provides risk for trisomy 18, Edwards syndrome)
Nuchal translucency screen at 11 weeks 3 days to 13 weeks 6 days.

Second trimester serum screening:

Beta HCG, unconjugated oestriol, alpha-fetoprotein and inhibin A ideally at 15 to 17 weeks; also gives risk for Edward syndrome and neural tube defects (NTD).

Definitions:

Levels of Evidence

Level	Explanation
I	Evidence obtained from a systematic review of level II studies
II	Evidence obtained from a randomised controlled trial (RCT)
III–1	Evidence obtained from a pseudo-randomised controlled trial (i.e., alternate allocation or some other method)
III–2	Evidence obtained from a comparative study with concurrent controls: • Non-randomised, experimental trial • Cohort study • Case–control study • Interrupted time series with a control group
III–3	Evidence obtained from a comparative study without concurrent controls: • Historical control study • Two or more single arm study • Interrupted time series without a parallel control group
IV	Case series with either post-test or pre-test/post-test outcomes
Practice Point	Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees

Grades of Recommendations

Grade	Explanation
A	Body of evidence can be trusted to guide practice
B	Body of evidence can be trusted to guide practice in most situations
C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
D	Body of evidence is weak and recommendation must be applied with caution

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Genetically determined diseases, including:

- Breast and ovarian cancer
- Colon cancer
- Familial hypercholesterolaemia (FH)
- Cystic fibrosis
- Down syndrome
- Hereditary haemochromatosis (HFE)
- Haemoglobinopathies and thalassaemias
- Fragile X syndrome

Guideline Category

Counseling

Diagnosis

Prevention

Risk Assessment

Screening

Clinical Specialty

Cardiology

Family Practice

Hematology

Medical Genetics

Obstetrics and Gynecology

Oncology

Pediatrics

Preventive Medicine

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

Public Health Departments

Guideline Objective(s)

- To facilitate evidence-based preventive activities for genetic counseling and testing in primary care
- To provide a comprehensive and concise set of recommendations for patients in general practice with additional information about tailoring risk and need
- To provide the evidence base for which primary healthcare resources can be used efficiently and effectively while providing a rational basis to ensure the best use of time and resources in general practice

Target Population

Any individual living in Australia considered to be at increased risk for a genetically determine disease, including the following subgroups:

- Pregnant women
- Couples planning a pregnancy
- Neonates

Interventions and Practices Considered

Risk factor assessment, genetic testing, counselling and referral for the following diseases:

- Breast and ovarian cancer
- Colon cancer
- Familial hypercholesterolaemia (FH)
- Cystic fibrosis
- Down syndrome
- Hereditary haemochromatosis (HFE)
- Haemoglobinopathies and thalassaemias
- Fragile X syndrome

Major Outcomes Considered

Risk for genetically determined diseases

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Sources of Recommendations

The recommendations in these guidelines are based on current, evidence-based guidelines for preventive activities. The Taskforce focused on those most relevant to Australian general practice. Usually this means that the recommendations are based on Australian guidelines such as those endorsed by the National Health and Medical Research Council (NHMRC).

In cases where these are not available or recent, other Australian sources have been used, such as guidelines from the Heart Foundation, Canadian or United States preventive guidelines, or the results of systematic reviews. References to support these recommendations are listed. However, particular references may relate to only part of the recommendation (e.g., only relating to one of the high-risk groups listed) and other references in the section may have been considered in formulating the overall recommendation.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence

Level	Explanation
I	Evidence obtained from a systematic review of level II studies
II	Evidence obtained from a randomised controlled trial (RCT)
III–1	Evidence obtained from a pseudo-randomised controlled trial (i.e., alternate allocation or some other method)
III–2	Evidence obtained from a comparative study with concurrent controls: • Non-randomised, experimental trial • Cohort study • Case–control study • Interrupted time series with a control group
III–3	Evidence obtained from a comparative study without concurrent controls: • Historical control study • Two or more single arm study • Interrupted time series without a parallel control group
IV	Case series with either post-test or pre-test/post-test outcomes

Level	Explanation
Practice Point	Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

These *Guidelines for preventive activities in general practice*, 8th edition, have been developed by a taskforce of general practitioners (GPs) and experts to ensure that the content is the most valuable and useful for GPs and their teams. The guidelines provide an easy, practical and succinct resource. The content broadly conforms to the highest evidence-based standards according to the principles underlying the Appraisal of Guidelines Research and Evaluation.

The dimensions addressed are:

- Scope and purpose
- Clarity of presentation
- Rigour of development
- Stakeholder involvement
- Applicability
- Editorial independence

The Red Book maintains developmental rigour, editorial independence, relevance and applicability to general practice.

Screening Principles

The World Health Organization (WHO) has produced guidelines for the effectiveness of screening programs. The Taskforce has kept these and the United Kingdom National Health Services' guidelines in mind in the development of recommendations about screening and preventive care.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendations

Grade	Explanation
A	Body of evidence can be trusted to guide practice
B	Body of evidence can be trusted to guide practice in most situations
C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
D	Body of evidence is weak and recommendation must be applied with caution

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

Not stated

Evidence Supporting the Recommendations

References Supporting the Recommendations

American College of Obstetricians and Gynecologists (ACOG). Screening for fetal chromosomal abnormalities. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2007 Jan. 11 p. (ACOG practice bulletin; no. 77). [43 references] PubMed

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The Cardiac Society of Australia and New Zealand. Guidelines for the diagnosis and management of familial hypercholesterolaemia. [internet]. CSANZ; 2010 [accessed 2012 Apr 01].

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Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of genetic counselling and testing in at-risk patient groups

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

- The information set out in this publication is current at the date of first publication and is intended for use as a guide of a general nature only and may or may not be relevant to particular patients or circumstances. Nor is this publication exhaustive of the subject matter. Persons implementing any recommendations contained in this publication must exercise their own independent skill or judgement or seek appropriate professional advice relevant to their own particular circumstances when so doing. Compliance with any recommendations cannot of itself guarantee discharge of the duty of care owed to patients and others coming into contact with the health professional and the premises from which the health professional operates.
- Whilst the text is directed to health professionals possessing appropriate qualifications and skills in ascertaining and discharging their professional (including legal) duties, it is not to be regarded as clinical advice and, in particular, is no substitute for a full examination and consideration of medical history in reaching a diagnosis and treatment based on accepted clinical practices.
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- These guidelines have not included detailed information on the management of risk factors or early disease (e.g., what medications to use in treating hypertension). Similarly, they have not made recommendations about tertiary prevention (preventing complications in those with established disease). Also, information about prevention of infectious diseases has been limited largely to immunisation and some sexually transmitted infections (STIs).

Implementation of the Guideline

Description of Implementation Strategy

For preventive care to be most effective, it needs to be planned, implemented and evaluated. Planning and engaging in preventive health is increasingly expected by patients. The Royal Australian College of General Practitioners (RACGP) thus provides the Red Book and *National guide to inform evidence-based guidelines*, and the Green Book (see the "Availability of Companion Documents" field) to assist in development of programs of implementation. The RACGP is planning to introduce a small set of voluntary clinical indicators to enable practices to monitor their preventive activities.

Implementation Tools

Chart Documentation/Checklists/Forms

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Genetic counselling and testing. In: Guidelines for preventive activities in general practice, 8th edition. East Melbourne (Australia): Royal Australian College of General Practitioners; 2012. p. 14-6.

Adaptation

This guideline has been partially adapted from Australian, Canadian, United Kingdom, and/or United States preventive guidelines.

Date Released

2012

Guideline Developer(s)

Royal Australian College of General Practitioners - Professional Association

Source(s) of Funding

Royal Australian College of General Practitioners

Guideline Committee

Red Book Taskforce

Composition of Group That Authored the Guideline

Taskforce Members: Dr Evan Ackermann (*Chair*), Chair, National Standing Committee for Quality Care, RACGP; Professor Mark Harris, Centre for Primary Health Care and Equity, University of New South Wales, National Standing Committee for Quality Care, RACGP; Dr Karyn Alexander, General practitioner, Victoria; Dr Meredith Arcus, General practitioner, Western Australia; Linda Bailey, Project Manager, Red Book Taskforce; Dr John Bennett, Chair, National Standing Committee for e-Health, RACGP; Associate Professor Pauline Chiarelli, School of Health Sciences, University of Newcastle, New South Wales; Professor Chris Del Mar, Faculty of Health Sciences and Medicine, Bond University, Queensland; Professor Jon Emery, School of Primary, Aboriginal and Rural Health Care, The University of Western Australia, National Standing Committee for Research, RACGP; Dr Ben Ewald, School of Medicine and Public Health, University of Newcastle, New South Wales; Dr Dan Ewald, General practitioner, New South Wales, Adjunct Associate Professor, Northern Rivers University Centre for Rural Health, and Clinical Advisor North Coast NSW Medicare Local; Professor Michael Fasher, Adjunct Associate Professor, University of Sydney, and Conjoint Associate Professor, University of Western Sydney, New South Wales; Dr John Furler, Department of General Practice, The University of Melbourne, Victoria; Dr Faline Howes, General practitioner, Tasmania; Dr Caroline Johnson, Department of General Practice, The University of Melbourne, Victoria, National Standing Committee for Quality Care, RACGP; Dr Beres Joyner, General practitioner, Queensland; Associate Professor John Litt, Department of General Practice, Flinders University, South Australia, Deputy Chair, National Standing Committee for Quality Care, RACGP; Professor Danielle Mazza, Department of General Practice, School of Primary Care, Monash University, Victoria, National Standing Committee for Quality Care, RACGP; Professor Dimity Pond, School of Medicine and Public Health, University of Newcastle, New South Wales; Associate Professor Lena Sanci, Department of General Practice, The University of Melbourne, Victoria; Associate Professor Jane Smith, Faculty of Health Sciences and Medicine, Bond University, Queensland; Dr Tania Winzenberg, Deputy Chair, National Standing

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Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Royal Australian College of General Practitioners (RACGP) Web site .

Availability of Companion Documents

The following are available:

- Preventive activities over the lifecycle – adults. Preventive activities over the lifecycle – children. Electronic copies: Available in Portable Document Format (PDF) from the Royal Australian College of General Practitioners (RACGP) Web site .
- Putting prevention into practice (green book). East Melbourne (Australia): Royal Australian College of General Practitioners; 2006. 104 p. Electronic copies: Available in PDF from the RACGP Web site .
- National guide to a preventive health assessment for Aboriginal and Torres Strait Islander people. East Melbourne (Australia): Royal Australian College of General Practitioners; 2012. 100 p. Electronic copies: Available in PDF from the RACGP Web site .

In addition, Appendix 1 of the original guideline document provides the Dutch Lipid Clinic Network Criteria for making a diagnosis of familial hypercholesterolaemia (FH) in adults and the Modified UK Simon Broome criteria for FH.

Patient Resources

None available

NGC Status

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